## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation,	)
and THE CURATORS OF THE UNIVERSITY	)
OF MISSOURI, a public corporation and body	)
politic of the State of Missouri,	)
	)
Plaintiffs,	)
	) C.A. No. 07-551-GMS
V.	)
	)
PAR PHARMACEUTICAL, INC.,	)
a Delaware corporation,	)
	)
Defendants	)

#### ANSWER AND COUNTERCLAIMS

Defendant, Par Pharmaceutical, Inc. ("Par"), by their attorneys, respond to the averments made in the numbered paragraphs of the first amended complaint ("complaint") filed by Plaintiffs, Santarus, Inc. and The Curators of the University of Missouri (collectively "Plaintiffs"), as follows:

#### ANSWER

Complaint Paragraph 1: Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Santarus is a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the prevention and treatment of gastrointestinal diseases and disorders.

Answer: On information and belief, Par admits that Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Par is without sufficient information to admit or deny the remaining allegations of paragraph 1 and, therefore, denies the same.

Complaint Paragraph 2: The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

Answer: On information and belief, Par admits that The University of Missouri has a place of business at 321 University Hall, Columbia, Missouri 65211. Par is without sufficient information to admit or deny the remaining allegations of paragraph 2 and, therefore, denies the same.

Complaint Paragraph 3: Plaintiffs are informed and believe, and thereon allege, that Defendant is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Defendant is one of the largest manufacturers and distributors of generic pharmaceutical products. Defendant conducts business throughout the United States, including in this District.

Answer: Par admits the allegations in the first and third sentences of paragraph 3. Par admits that it manufactures and distributes, *inter alia*, generic pharmaceutical products in the United States, and states that its size is a matter of public record. Par denies any remaining allegations of Paragraph 3.

Complaint Paragraph 4: This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, et seq., including § 271. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

Answer: In response to the allegations of paragraph 4, Par admits that Plaintiffs purport to bring this action under Title 35, United States Code. Par states that it does not contest subject-matter jurisdiction. Par denies the remaining allegations in paragraph 4, and expressly denies any allegation of patent infringement and denies that Plaintiffs are entitled to any relief.

<u>Complaint Paragraph 5</u>: Defendant is subject to personal jurisdiction in this District because it is incorporated in Delaware, conducts business in this District, purposefully avails itself of the rights and benefits of Delaware law, and has substantial and continuing contacts with Delaware.

Answer: In response to the allegations in paragraph 5, Par states that it does not contest personal jurisdiction in Delaware for the purposes of this action.

Complaint Paragraph 6: Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

Answer: In response to the allegations of paragraph 6, Par states that it does not contest venue in this judicial district for the purposes of this action.

Complaint Paragraph 7: On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885, entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips.

Answer: In response to paragraph 7 of the complaint, Par states that the face of the '885 patent speaks for itself with respect to the date of issue, the title, and the named inventor. Par is without sufficient information to admit or deny the remaining allegations in paragraph 7, and therefore denies the same.

Complaint Paragraph 8: On or about August 22, 2005, reexamination of U.S. Patent No. 6,699,885 by the PTO was requested by a third party, which was granted by the PTO. On or about March 13, 2007, the reexamination proceedings concluded with the PTO issuing a Notice of Intent to Issue a Reexamination Certificate confirming that all claims of the patent "are determined to be patentable as amended." On September 18, 2007, the PTO issued a

Reexamination Certificate confirming that all claims as amended are "determined to be patentable." In the Reexamination Certificate, claims 1 and 26 were amended, and claims 52 and 53 were added. A copy of the U.S. Patent No. 6,669,885 and its Ex Parte Reexamination Certificate (5894th) are attached hereto as Exhibits A and B, respectively, and shall be hereafter referred to collectively as the "885 Patent."

Answer: In response to paragraph 8 of the complaint, Par admits only (1) that PTO records state that on or about August 22, 2005, a request for reexamination of the '885 Patent was filed with the PTO and was subsequently granted by the PTO, (2) on or about March 13, 2007, the PTO records indicate that the PTO issued a Notice of Intent to Issue a Reexamination Certificate, (3) PTO records indicate that on September 18, 2007, the PTO issued a Reexamination Certificate, (4) PTO records indicate that during the Reexamination proceedings, claims 1 and 26 were amended, and claims 52 and 53 were added. Par also admits that what appears to be a copy of the '885 patent is attached as Exhibit A to the complaint and what appears to be a copy of Ex Parte Reexamination Certificate (5894th) is attached to the complaint as Exhibit B. Par is denies the remaining allegations of paragraph 8.

Complaint Paragraph 9: On December 3, 2002, the PTO issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '346 Patent is attached hereto as Exhibit C.

Answer: In response to paragraph 9 of the complaint, Par admits only that what appears to be a copy of the '346 patent is attached as Exhibit C to the complaint and states that the face of the '346 patent speaks for itself with respect to the issue date, the title and the named inventor. Par denies any remaining allegations in paragraph 9.

Complaint Paragraph 10: On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '988 Patent is attached hereto as Exhibit D.

Answer: In response to paragraph 10 of the complaint, Par admits only that what appears to be a copy of the '988 patent is attached as Exhibit D to the complaint and states that the face of the '988 patent speaks for itself with respect to the issue date, the title, and the named inventor. Par denies any remaining allegations in paragraph 10.

Complaint Paragraph 11: The University is the record owner of the '885, '346, and '988 patents (collectively the "Patents-in-Suit"), and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce the Patents-in-Suit.

Answer: Par is without information sufficient to admit or deny the allegations of paragraph 11 and, therefore, denies the same.

Complaint Paragraph 12: The Patents-in-Suit are listed in the United States Food and Drug Administration's (the "FDA") Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, in support of Santarus' Zegerid® (omeprazole/sodium bicarbonate) Capsules 20 mg and 40 mg ("Zegerid®") products. Zegerid® is indicated for the treatment of heartburn and other symptoms of gastroesophageal reflux disease, the treatment and maintenance of healing of erosive esophagitis, and the short-term treatment of active duodenal ulcers and active benign gastric ulcers. Zegerid® is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid® is marketed by Santarus.

Answer: With respect to paragraph 12 of the complaint, Par admits only that it appears that Santarus caused the Patents-in-Suit to be listed in the FDA Orange Book with respect to

Santarus's Zegerid<sup>®</sup> (omeprazole/sodium bicarbonate) Capsules 20 mg and 40 mg ("Zegerid<sup>®</sup>") products and that the labeling for NDA No. 21-849 approved on February 27, 2006 states that Zegerid<sup>®</sup> is indicated for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease, the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy, to maintain healing of erosive esophagitis, the short-term treatment of active duodenal ulcer, and the short-term treatment (4-8 weeks) of active benign gastric ulcer. Par is without sufficient information to admit or deny the remaining allegations of paragraph 12 and, therefore, denies the same.

Complaint Paragraph 13: On information and belief, Defendant has submitted Abbreviated New Drug Application No. 78-966 (the "ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market omeprazole and sodium bicarbonate capsules, 20 mg/1100 mg and 40 mg/1100 mg (the "Proposed Capsules"), a generic version of Zegerid<sup>®</sup>, prior to the July 16, 2016, expiration of the Patents-in-Suit.

Answer: Par admits the allegations of the first sentence of paragraph 13. Par admits that it has requested FDA to approve the ANDA before the July 16, 2016 expiration of the patents-insuit, and that the ANDA product is omeprazole and sodium bicarbonate capsules, 20mg/1100mg, and 40 mg/1100mg. Par denies the remaining allegations of paragraph 13.

Complaint Paragraph 14: Plaintiffs received a letter dated August 2, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed Capsules.

Answer: On information and belief, Par admits the allegations of paragraph 14.

Complaint Paragraph 15: Plaintiffs commenced this action within 45 days of receiving the Paragraph IV Certification.

Answer: Par is without sufficient information to admit or deny the allegations of paragraph 15 and, therefore, denies the same.

Complaint Paragraph 16: Plaintiffs incorporate by reference paragraphs 1 through 15.

Answer: Par's responses to the allegations of paragraphs 1 through 15 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 17: The submission of the ANDA to the FDA, including the Paragraph IV Certification, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Capsules would infringe the '885 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 17.

Complaint Paragraph 18: Defendant has been aware of the existence of the '885 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed Capsules will not infringe the '885 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '885 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 18.

Complaint Paragraph 19: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 19.

Complaint Paragraph 20: Plaintiffs incorporate by reference paragraphs 1 through 15.

Answer: Par's responses to the allegations of paragraphs 1 through 15 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 21: The submission of the ANDA to the FDA, including the Paragraph IV Certification, constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Capsules would infringe the '346 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 21.

Complaint Paragraph 22: Defendant has been aware of the existence of the '346 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed Capsules will not infringe the '346 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '346 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 22.

Complaint Paragraph 23: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 23.

Complaint Paragraph 24: Plaintiffs incorporate by reference paragraphs 1 through 15.

Answer: Par's responses to the allegations of paragraphs 1 through 15 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 25: The submission of the ANDA to the FDA, including the Paragraph IV Certification, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Capsules would infringe the '988 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 25.

Complaint Paragraph 26: Defendant has been aware of the existence of the '988 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed Capsules will not infringe the '988 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '988 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 26.

Complaint Paragraph 27: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 27.

### RESPONSE TO PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to any of the relief that it seeks in its prayer for relief or otherwise.

#### **DEFENSES**

Without any admission as to the burden of proof or as to any of the allegations in the Complaint, Par states the following defenses.

### First Defense

Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

#### Second Defense

1. Par's omeprazole and sodium bicarbonate capsules that are the subject of ANDA No. 78-966 (the "Proposed Products") do not infringe, and would not infringe, (directly, indirectly, contributorily or by inducement) any valid or enforceable claim of the Patents-in-Suit.

#### Third Defense

2. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the application that led to the issuance of the Patents-in-Suit, the Patents-in-Suit are so limited that no claim can be construed as covering any Par activity.

#### Fourth Defense

3. Each and every asserted claim of the Patents-in-Suit is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including Sections 101, 102, 103, and 112 and for improper double patenting.

#### Fifth Defense

4. Par's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

### Sixth Defense

5. Par has not willfully infringed any claim of the Patents-in-Suit.

#### **Seventh Defense**

6. Plaintiff's claims and requested relief are barred by the doctrine of estoppel.

#### **Eighth Defense**

7. Plaintiff's claims and requested relief are barred by the doctrine of waiver.

#### Ninth Defense

8. Plaintiff's claims and requested relief are barred by the doctrine of laches.

#### Tenth Defense

- 9. The Patents-in-Suit are unenforceable due to the inequitable conduct of The University of Missouri and/or J. Owen Phillips, Santarus, and/or their employees, agents, and attorneys.
- 10. United States Patent Application No. 08/680,376 ("the '376 application") was filed on July 15, 1996 and issued as U.S. Patent No. 5,840,737 ("the '737 patent") on November 24, 1998.
- During prosecution of the '376 application, the applicant failed to disclose material prior art with the intention of deceiving the Patent Office.
- 12. For example, the applicant disclosed approximately 61 material prior art references during prosecution of the '376 application.
- However, the applicant disclosed over 230 material prior art references during prosecution of the later '207 application, which was filed on January 11, 2000. The '207 application is a parent application to each of the patents-in-suit.
- 14. The applicant gave no explanation for why material prior-art references disclosed in the '207 application were not disclosed during prosecution of the '376 application.
- 15. The applicant could not claim to have been ignorant of this prior art during prosecution of the '376 application because the prior art included the applicant's own work.
- 16. For example, during prosecution of the '376 application the applicant withheld from the Patent Office a presentation to the University of Missouri Surgical Society dated June of 1994 (the "1994 presentation"), which discussed the use of a simplified omegrazole solution.
- 17. The 1994 presentation occurred approximately two years before the applicant filed United States Provisional Application No. 60/009,608 ("the Provisional Application") on

- January 4, 1996, which is the earliest application from which the applicant purports to claim priority.
- 18. The 1994 presentation disclosed, *inter alia*, a "simplified omeprazole solution" of omeprazole powder and sodium bicarbonate powder dissolved in water.
- 19. Furthermore, during prosecution of the '376 application, the applicant failed to disclose that in October 1993 and in 1994, the patentee discussed the possibility of performing a multi-center study using SOS with a group of 19 scientists.
- During prosecution of the '376 application, the applicant failed to disclose that he had disclosed to other scientists in 1994 how to make and use SOS.
  - 21. The other scientists were under no obligation of secrecy to the inventor.
- These disclosures occurred more than one year before the applicant filed the Provisional Application.
- 23. Disclosures of this kind are printed publications within the meaning of 35 U.S.C. § 102(b).
- 24. These disclosures constituted a public use of every claim in the '376 application within the meaning of 35 U.S.C. § 102(b).
  - 25. These disclosures would have been material to a reasonable examiner.
- 26. On information and belief, the '346 patent issued from U.S. Patent Application No. 09/481,207 ("the '207 application"), filed on January 11, 2000.
- On information and belief, the '207 application was filed as a continuation-in-part of United States Patent Application No. 09/183,422 ("the '422 application"), filed on October 30, 1998.

- On information and belief, the '422 application was filed as a continuation-in-part of the '376 application.
- On information and belief, the '988 patent issued from United States Patent Application No. 09/901,942 ("the '942 application"), filed on July 9, 2001.
- 30. On information and belief, the '942 application was filed as a continuation-in-part of the '207 application.
- 31. On information and belief, the '885 patent issued from United States Patent Application No. 10/054,350 ("the '350 application"), filed January 19, 2002.
- 32. On information and belief, the '350 application was filed as a continuation-in-part of the '942 application.
- 33. The applicant withheld material prior art references and information until almost two years after the '207 application was filed.
- 34. The applicant's delay in submitting this material information is inequitable conduct.
- 35. In addition, the applicant's failure to disclose material prior-art references during prosecution of the '737 patent creates an infectious unenforceability of the '988, '885 and '346 patents.
- 36. There is an immediate and necessary relation between the claims of the '737 patent and the claims of the '988, '885 and '346 patents.
- 37. Therefore, the applicant's inequitable conduct during the prosecution of the '737 patent renders the '988, '885 and '346 patents unenforceable as well.
- The application that resulted in the '737 patent was a parent of the '988, '885 and '346 patents.

- 39. Furthermore, the claims of the '988, '885 and '346 patents are not patentably distinct over the claims of the '737 patent.
  - 40. The '346 patent contains a terminal disclaimer over the '737 patent.
- 41. The terminal disclaimer acts as an admission that the '346 patent's claims are not patentably distinct from the claims of the '737 patent.
- The '885 patent contains a terminal disclaimer over the '737 patent and the '346 patent.
- The terminal disclaimer acts as an admission that the '885 patent's claims are not patentably distinct from the claims of the '737 patent and the '346 patent.
- The '988 patent contains a terminal disclaimer over any patent issuing from the '207 application.
  - On information and belief, the '346 patent issued from the '207 patent.
- Therefore, the patentee has admitted that the claims of the '346 patent and the claims of the '988 patent are patentably indistinct from one another.
- The patentee has also admitted that the claims of the '737 patent and the '346 patent are patentably indistinct from one another.
- There is, therefore, an immediate and necessary relation between the claims of the '737 patent and the claims of the '988, '885 and '346 patents.
- Therefore, the applicant's inequitable conduct during the prosecution of the '737 patent renders the '988, '885 and '346 patents unenforceable.

### **COUNTERCLAIMS**

Par, by way of counterclaim against Plaintiffs, alleges:

#### The Parties

- 1. Par is a Delaware corporation with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
- 2. On information and belief, Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130.
- 3. On information and belief, The University of Missouri is a corporation having a place of business at 321 University Hall, Columbia, Missouri 65211.

#### **Jurisdiction**

- 4. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief, *i.e.*, a declaration that the Patents-in-Suit are not infringed and that they are invalid and unenforceable.
- 5. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 6. Santarus and The University of Missouri, by bringing this action in this district, have consented to and are subject to personal jurisdiction in this district.

#### Factual Background

- 7. United States Patent No. 6,645,988 ("the '988 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on November 11, 2003.
- 8. United States Patent No. 6,489,346 ("the '346 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on December 3, 2002.

- 9. United States Patent No. 6,699,885 ("the '885 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on March 2, 2004.
- Upon information and belief, the '988 patent, the '346 patent, and the '885 patent (collectively the "Patents-in-Suit,") are assigned to The Curators of the University of Missouri.
  - 11. Plaintiffs have alleged that the Patents-in-Suit are licensed to Santarus.
- 12. The Patents-in-Suit purport to relate to various combinations of omeprazole and sodium bicarbonate.
- 13. Par submitted ANDA No. 78-966 for omeprazole to the Food and Drug Administration ("FDA").
- 14. Par's ANDA includes confidential information concerning Par's omeprazole capsules.

# FIRST COUNT (Declaration of Non-Infringement of the Patents-in-Suit)

- 15. Par repeats and realleges paragraphs 1 through 14 of the counterclaim.
- Par denies -- that the claims of the Patents-in-Suit against Par. Plaintiffs maintain -- and Par denies -- that the claims of the Patents-in-Suit cover Par's Proposed Products.
- The claims of the Patents-in-Suit do not, either literally or under the doctrine of equivalents, cover Par's Proposed Products. Thus, Par has not infringed and will not infringe any claim of the Patents-in-Suit by making, using, selling, offering for sale, marketing, or importing the Proposed Products.
- 18. This is an action brought under the Declaratory Judgment Act, 28 U.S.C. §2201 and 2202 and the Patent Laws of the United States, 35 U.S.C. §1 *et seq* based upon an actual controversy between the parties to declare that Par is free to seek final FDA approval of ANDA

No., 78-966 and upon approval to manufacture, use, market, sell, offer to sell, and/or import the products that are the subject of that ANDA.

19. Par is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products does not infringe any of the Patents-in-Suit.

## SECOND COUNT (Declaration of Invalidity of the Patents-in-Suit)

- 20. Par repeats and realleges paragraphs 1 through 19 of the counterclaim.
- 21. The Patents-in-Suit and all their claims are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or for double patenting.
  - 22. Plaintiffs maintain -- and Par denies -- that the Patents-in-Suit are valid.
- 23. Par and Plaintiffs have adverse legal interests, and there is a substantial controversy between Plaintiffs and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the Patents-in-Suit.
  - 24. Par is entitled to a judicial declaration that the Patents-in-Suit are invalid.

## THIRD COUNT (Declaration of Unenforceability of the Patents-in-Suit Due to Inequitable Conduct)

- 25. Par repeats and realleges paragraphs 1 through 24 of the counterclaim.
- 26. The Patents-in-Suit and all their claims are unenforceable due to inequitable conduct.
- 27. Par repeats and realleges paragraphs 10 through 50 of its defenses, in which the factual basis for Par's allegations that the Patents-in-Suit and all their claims are unenforceable due to inequitable conduct are set forth with particularity.

WHEREFORE, Par demands judgment in its favor and against Santarus, Inc. and The Curators of the University of Missouri as follows:

- (a) Dismissing the complaint with prejudice and denying each request for relief made by Santarus, Inc. and/or The Curators of the University of Missouri;
- (b) Declaring the '988 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;
- (c) Declaring the '346 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;
- (d) Declaring the '885 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;
  - (e) Declaring the '988 patent and all its claims invalid;
  - (f) Declaring the '346 patent and all its claims invalid;
  - (g) Declaring the '885 patent and all its claims invalid;
  - (h) Declaring the '988 patent and all its claims unenforceable;
  - (i) Declaring the '346 patent and all its claims unenforceable;
  - (j) Declaring the '885 patent and all its claims unenforceable;
  - (k) Adjudging this to be an exceptional case under 35 U.S.C. § 285;
  - (l) awarding Par its attorneys' fees;
  - (m) Awarding Par its costs and expenses; and
  - (n) Awarding Par such other and further relief as the Court deems just and proper.

Of Counsel: Edgar H. Haug Daniel G. Brown Frommer Lawrence & Haug LLP 745 Fifth Avenue New York, New York 10151 (212) 588-0800

Dated: October 17, 2007

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## IN THE UNITED STATES DISTRICT COURT DISTRICT OF DELAWARE

#### **CERTIFICATE OF SERVICE**

I hereby certify that on October 17, 2007, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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